

Original Research Article

A COMPARATIVE STUDY BETWEEN FENTANYL AND TRAMADOL AS ADJUVANT TO 0.1% BUPIVACAINE FOR EPIDURAL LABOUR ANALGESIA

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ABSTRACT

Background: Labour pain is one of the most intense forms of pain experienced by women and is associated with significant physiological and psychological stress. Effective pain relief during labour improves maternal comfort, reduces stress responses, and enhances the overall childbirth experience. Epidural analgesia is widely considered the gold standard for labour pain relief because it provides superior analgesia while allowing the mother to remain conscious and actively participate in the birthing process. The addition of opioid adjuvants such as fentanyl or tramadol to local anaesthetics like bupivacaine enhances analgesic efficacy while reducing the dose requirement of local anaesthetics. **Aim:** To compare the efficacy and safety of epidural administration of bupivacaine with fentanyl versus bupivacaine with tramadol for labour analgesia.

Materials and Methods: This prospective, randomized, patient and observer-blinded study was conducted in the Department of Anaesthesiology in association with the Department of Obstetrics and Gynaecology at GS Medical College and Hospital, Hapur, for the period of 18 months. Ninety ASA II parturients aged 18–35 years with uncomplicated singleton pregnancies in active labour were included. Patients were randomly divided into two groups of 45 each. Group F received epidural bupivacaine 10 ml of 0.125% with fentanyl 20 µg, while Group T received epidural bupivacaine 10 ml of 0.125% with tramadol 20 mg. **Results:** The onset of analgesia was significantly faster in the fentanyl group (5.76 ± 2.57 minutes) compared with the tramadol group (8.00 ± 3.04 minutes) ($p < 0.001$). The duration of analgesia was significantly longer in the fentanyl group (183.67 ± 43.34 minutes) compared with the tramadol group (145.98 ± 52.15 minutes) ($p < 0.001$). Both groups showed comparable VAS scores throughout labour. Maternal hemodynamic parameters remained stable in both groups. The duration of labour stages, mode of delivery, and neonatal APGAR scores were similar between the groups. However, maternal adverse effects such as pruritus, nausea, vomiting, hypotension, and urinary retention were significantly more frequent in the fentanyl group. The tramadol group required more repeat analgesic doses due to shorter duration of analgesia. **Conclusion:** Epidural bupivacaine with fentanyl provides faster onset and longer duration of labour analgesia compared with bupivacaine with tramadol. However, fentanyl is associated with a higher incidence of maternal adverse effects. Tramadol provides effective analgesia with fewer side effects but requires more frequent dosing. Both regimens are safe with respect to maternal hemodynamic stability, labour progression, and neonatal outcomes.

Keywords: Labour analgesia, Epidural analgesia, Bupivacaine, Fentanyl, Tramadol, Visual Analogue Scale, Obstetric anaesthesia.

INTRODUCTION

Labour is a complex physiological process accompanied by progressively increasing pain arising from uterine contractions, cervical dilatation, stretching of the lower uterine segment, and distension of the pelvic floor and perineal structures. The intensity and perception of labour pain vary considerably among parturients and are influenced by parity, stage of labour, maternal anxiety, previous experience, fetal position, and individual pain threshold. Severe inadequately controlled labour pain can initiate marked sympathetic activation with increases in circulating catecholamines, maternal oxygen consumption, heart rate, blood pressure, and ventilation. Effective pain relief is therefore an important component of contemporary obstetric care and aims to provide maternal comfort while preserving maternal consciousness, mobility as far as possible, effective uterine activity, and fetal well-being.^[1] Several pharmacological and non-pharmacological methods are available for the management of labour pain. Pharmacological options include systemic opioids, inhalational agents, and neuraxial techniques, whereas non-pharmacological measures include breathing exercises, relaxation techniques, massage, positioning, and psychological support. Among these approaches, neuraxial analgesia provides the most reliable and titratable form of pain relief during labour. Epidural analgesia permits administration of analgesic drugs through an epidural catheter and allows repeated dosing according to the changing analgesic requirements of the parturient. The technique can be continued throughout labour and can also provide an established neuraxial route if operative intervention becomes necessary.^[2] Local anaesthetics form the foundation of epidural labour analgesia. Bupivacaine has been widely used because of its potent sensory-blocking properties and relatively prolonged duration of action. However, higher concentrations can produce greater motor blockade, which may interfere with maternal mobility and bearing-down efforts. Modern obstetric epidural practice has therefore progressively moved toward the use of low concentrations of local anaesthetics, frequently combined with suitable analgesic adjuvants. Low-concentration solutions are intended to provide effective sensory analgesia while limiting excessive motor blockade and reducing the total requirement for local anaesthetic. A concentration of 0.1% bupivacaine represents one such low-concentration approach suitable for combination with an analgesic adjuvant.^[3] Opioid adjuvants are commonly combined with local anaesthetics during neuraxial labour analgesia because the two drug classes act through different mechanisms and can complement each other. Fentanyl is a potent synthetic opioid with high lipid solubility and predominantly μ -opioid receptor activity. Its physicochemical characteristics favour a relatively rapid onset after neuraxial

administration. When used with a dilute local anaesthetic such as bupivacaine, fentanyl can contribute to analgesia without requiring a substantial increase in local anaesthetic concentration. Nevertheless, neuraxial opioids may be associated with adverse effects such as pruritus, nausea, vomiting, sedation, urinary retention, and respiratory depression, making careful maternal monitoring necessary during their use.^[4] Fentanyl has been extensively incorporated into different labour analgesic techniques, including epidural, combined spinal-epidural, intrathecal, and systemic approaches. Its role as an opioid component of epidural solutions has been established because the addition of an opioid may improve analgesic quality while permitting the use of lower concentrations of local anaesthetic. Selection of the opioid dose and method of administration requires consideration of maternal analgesia, maternal haemodynamic stability, respiratory status, progress of labour, fetal condition, and neonatal well-being. Continuous observation remains essential because labour itself is dynamic and analgesic requirements can change substantially as cervical dilatation progresses and the presenting part descends.^[5] Tramadol is another centrally acting analgesic with a pharmacological profile different from that of conventional potent opioids. It has weak agonistic activity at μ -opioid receptors and also influences descending inhibitory pain pathways through inhibition of serotonin and norepinephrine reuptake. These combined mechanisms contribute to its analgesic activity. Tramadol has been administered through different routes for acute and perioperative pain management and has also been investigated as an adjuvant in regional and neuraxial analgesic techniques. Its pharmacological differences from fentanyl provide a basis for comparing the two drugs when used as adjuncts to a local anaesthetic. Consideration of efficacy must be accompanied by evaluation of possible adverse effects, particularly nausea, vomiting, neurological effects, and other opioid-related complications.^[6]

MATERIALS AND METHODS

After obtaining approval from the Institutional Ethical Committee, written informed consent was obtained from all participants according to the principles of the Declaration of Helsinki. The procedure, expected benefits, and possible adverse effects related to the study were explained to each participant before enrolment. The present study was designed as a prospective, randomized, double-blinded comparative study. The study was conducted in the Labour Room of G S Medical College and Hospital, Pilkhuwa, Hapur, Uttar Pradesh. Thus, a total of 90 patients were included in the study.

Inclusion Criteria

Patients who provided written informed consent, belonged to American Society of Anesthesiologists

physical status grade II, were aged between 18 to 35 years, and were either primigravidae or second gravida without associated comorbidities were included in the study. Patients with cervical dilatation of 3–5 cm in active labour, cephalic presentation, gestational age of more than 37 weeks, and height greater than 150 cm were considered eligible for inclusion.

Exclusion Criteria

Patients who refused to participate or were unable to comprehend the Visual Analogue Scale were excluded. Multiparous women, patients with multiple pregnancies, malpresentation, cephalopelvic disproportion, previous lower-segment caesarean section, history of allergy to any of the drugs used, coagulation disorders, and non-progression of labour were also excluded. High-risk pregnancies including severe anaemia, antepartum haemorrhage, preeclampsia, eclampsia, diabetes mellitus, cardiac or respiratory system involvement, and patients with a body mass index greater than 35 kg/m² were excluded from the study.

Methodology

Eligible patients were recruited directly from pregnant women admitted to the Department of Obstetrics and Gynaecology for normal vaginal delivery. Consecutive patients with uncomplicated singleton pregnancies were screened according to the predefined eligibility criteria. A total of 90 eligible pregnant women with uncomplicated singleton pregnancies were randomly allocated into two groups, Group F and Group T, with 45 patients in each group. Randomization was performed using a computer-generated block randomization sequence with variable-sized blocks. Allocation concealment was maintained using the opaque sealed-envelope technique. After the patient was shifted to the labour room, the sealed envelope was opened by a designated labour room technician. The study medication was prepared in identical syringes by a junior resident who was not involved in subsequent patient assessment. The patient, attending physician, and anaesthesiologist involved in assessment remained unaware of group allocation, and decoding was performed only after completion of data analysis. The methodology and epidural analgesia procedure were explained to all patients, and written informed consent was obtained. A detailed clinical history was recorded, followed by pre-anaesthetic evaluation and systemic examination. Height and weight were documented. On arrival in the labour room, baseline parameters were recorded, and standard monitoring comprising pulse rate, electrocardiography, peripheral oxygen saturation, and non-invasive systolic, diastolic, and mean arterial blood pressure was instituted.

An intravenous line was secured using an 18-gauge cannula, and 500 mL of Ringer's lactate solution was administered as preload. Patients were instructed regarding the use of a 10-cm linear Visual Analogue Scale, where a score of 0 represented no pain and a score of 10 represented the worst possible pain. The

patient was positioned in the left lateral position with the back perpendicular to the edge of the table and the hips and knees adequately flexed.

Epidural Technique: Under strict aseptic precautions, the patient's back was prepared from the lower thoracic region to the lower sacral region, including both flanks, and sterile draping was performed. The L3–L4 or L4–L5 intervertebral space was selected depending on convenience. After local infiltration with 2% lignocaine, an 18-gauge Tuohy needle was introduced through the midline with its bevel directed cephalad. The epidural space was identified by the loss-of-resistance-to-air technique. Gentle aspiration was performed to exclude the presence of blood or cerebrospinal fluid. Care was taken not to advance the needle through the ligamentum flavum during active uterine contractions.

Insertion and Fixation of Epidural Catheter: After identification of the epidural space, a 20-gauge multi-orifice epidural catheter was passed through the Tuohy needle with the bevel directed cephalad. Approximately 3–4 cm of the catheter was advanced into the epidural space. The needle was then carefully withdrawn while maintaining the position of the catheter. The catheter was secured at the skin puncture site using gauze and waterproof adhesive tape and was subsequently connected to the bacterial filter under sterile conditions.

Test Dose: The position of the epidural catheter was reconfirmed by aspiration. A test dose of 3 mL of 2% lignocaine containing 15 µg of epinephrine was administered to detect accidental intrathecal or intravascular placement. Patients were observed for subjective symptoms such as sensory or motor blockade of the lower limbs, dizziness, light-headedness and palpitations, as well as objective changes in blood pressure and heart rate.

Group F: Patients allocated to Group F received bupivacaine with fentanyl. The loading dose consisted of 10 mL of 0.125% bupivacaine with 20 µg of fentanyl. Subsequent top-up doses consisting of 10 mL of 0.125% bupivacaine with 20 µg of fentanyl were administered according to patient requirement.

Group T: Patients allocated to Group T received bupivacaine with tramadol. The loading dose consisted of 10 mL of 0.125% bupivacaine with 20 mg of tramadol. Subsequent top-up doses consisting of 10 mL of 0.125% bupivacaine with 20 mg of tramadol were administered according to patient requirement. The progress and different stages of labour were assessed with the assistance of the attending obstetrician.

Timing of Epidural Analgesia: Epidural analgesia was administered during the first stage of labour according to the requirement of the parturient. The stage of labour was determined in consultation with the obstetrician. The epidural drug was administered between uterine contractions to minimize the possibility of excessive drug spread within the epidural space. After administration of the initial loading dose, further top-up doses were administered

on patient demand until completion of the fourth stage of labour.

Assessment of Analgesia: The onset and duration of analgesia were recorded. Pain intensity was assessed using the Visual Analogue Scale, where 0 represented no pain and 10 represented the worst imaginable pain. T0 was considered the time of administration of the study drug. The onset of analgesia was assessed as the time required to achieve a VAS score of less than 3. Duration of analgesia was measured from T0 until the VAS score became greater than 3 or breakthrough pain occurred. Top-up doses were administered when the VAS score exceeded 3, and the total number of top-up doses required was recorded.

Maternal Monitoring: Maternal heart rate, respiratory rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and peripheral oxygen saturation were monitored. Blood pressure and heart rate were recorded before epidural administration and subsequently at 5, 10, 15, 20, 25, 30, and 60 minutes and thereafter every 30 minutes until delivery. Hypotension was defined as a decrease in mean arterial pressure of at least 20% from baseline and/or systolic blood pressure below 100 mmHg and was managed with intravenous fluid boluses and/or 6 mg ephedrine, which could be repeated when required. Bradycardia was defined as a heart rate below 60 beats/minute and was treated with 0.5 mg atropine.

Assessment of Adverse Effects: Patients were observed for respiratory depression, defined as a respiratory rate of 10 breaths/minute or less, as well as headache, pruritus, nausea, vomiting, hypotension, bradycardia, and urinary retention. Nausea and vomiting were treated with 10 mg metoclopramide, while pruritus was treated with 50 mg diphenhydramine. All complications associated with epidural labour analgesia were recorded.

Assessment of Labour and Mode of Delivery: Cervical dilatation at the commencement of the study, duration of the first and second stages of labour, and mode of delivery were recorded. The mode of delivery was categorized as spontaneous vaginal delivery, assisted vaginal delivery, or caesarean section.

Fetal and Neonatal Monitoring: Fetal heart rate was continuously monitored using cardiotocography. In the presence of fetal heart rate abnormalities, maternal oxygen supplementation or intravenous fluids were administered, oxytocin was discontinued, and left uterine displacement was ensured. Neonatal outcome was assessed using the Apgar score at 1 and 5 minutes after birth.

Maternal Satisfaction: Maternal satisfaction with labour analgesia was assessed using a three-point scale. A score of 0 represented an experience worse than anticipated, a score of 1 represented an experience as anticipated, and a score of 2 represented an experience better than anticipated.

RESULTS

Table 1. Baseline Demographic and Maternal Physiological Characteristics of Study Participants

Table 1 shows the baseline demographic and maternal physiological characteristics of the participants in Group F receiving fentanyl and Group T receiving tramadol. The mean age of participants was 28.96 ± 5.87 years in Group F and 28.64 ± 5.35 years in Group T, with no statistically significant difference between the groups ($p = 0.793$). The mean BMI was 25.41 ± 3.12 kg/m² in Group F and 24.61 ± 2.98 kg/m² in Group T, and the difference was not statistically significant ($p = 0.204$). All participants in both groups belonged to ASA physical status II. The mean gestational age was 38.60 ± 1.30 weeks in Group F and 39.13 ± 1.49 weeks in Group T, with a p value of 0.074. The mean cervical dilatation at the time of epidural insertion was 3.44 ± 0.86 cm in Group F and 3.57 ± 0.98 cm in Group T, with no statistically significant difference ($p = 0.510$). The baseline mean heart rate was 85.53 ± 9.55 bpm in Group F and 87.36 ± 9.68 bpm in Group T ($p = 0.371$).

Table 2. Analgesia Characteristics and Visual Analogue Scale Scores at Various Stages of Labour

Table 2 presents the onset and duration of analgesia along with Visual Analogue Scale scores at different stages of labour. The mean onset of analgesia was 5.76 ± 2.57 minutes in Group F compared with 8.00 ± 3.04 minutes in Group T. This difference was statistically significant ($p < 0.001$). The mean duration of analgesia was 183.67 ± 43.34 minutes in Group F and 145.98 ± 52.15 minutes in Group T, and this difference was also statistically significant ($p < 0.001$). During the latent phase of labour, the mean VAS score was 1.44 ± 1.37 in Group F and 1.56 ± 1.91 in Group T ($p = 0.652$). During the active phase, the respective VAS scores were 2.51 ± 1.60 and 2.64 ± 2.43 ($p = 0.748$). At full cervical dilatation, the mean VAS score was 1.76 ± 1.03 in Group F and 1.87 ± 1.77 in Group T ($p = 0.688$). At crowning, the mean VAS score was 0.60 ± 0.78 in Group F and 0.72 ± 1.23 in Group T ($p = 0.562$). During the third stage of labour, the mean VAS score was 0.64 ± 0.65 in Group F and 0.84 ± 0.80 in Group T ($p = 0.194$), while during the fourth stage it was 0.31 ± 0.47 and 0.27 ± 0.50 , respectively ($p = 0.663$).

Table 3. Labour Outcomes, Neonatal Parameters and Mode of Delivery

Table 3 summarizes labour outcomes, neonatal APGAR scores, and mode of delivery in the two groups. The mean duration of the first stage of labour was 299.40 ± 106.22 minutes in Group F and 324.20 ± 98.86 minutes in Group T, with no statistically significant difference between the groups ($p = 0.255$). The mean duration of the second stage of labour was 60.16 ± 28.79 minutes in Group F and 62.31 ± 32.01 minutes in Group T ($p = 0.738$). The mean APGAR

score at 1 minute was 8.13 ± 0.82 in Group F and 7.98 ± 0.87 in Group T, with a p value of 0.382. At 5 minutes, the mean APGAR score was 8.87 ± 0.82 in Group F and 9.02 ± 0.75 in Group T, with a p value of 0.350. Regarding mode of delivery, normal vaginal delivery occurred in 35 (77.8%) participants in Group F and 35 (77.8%) participants in Group T. Instrumental delivery occurred in 5 (11.1%) participants in Group F and 3 (6.7%) participants in Group T, while LSCS was performed in 5 (11.1%) participants in Group F and 7 (15.6%) participants in Group T.

Table 4. Intrapartum Maternal Monitoring Parameters

Table 4 depicts maternal heart rate, mean arterial pressure, oxygen saturation, and respiratory rate measured at different time intervals during labour. At 5 minutes, the mean heart rate was 86.89 ± 12.10 bpm in Group F and 91.71 ± 12.25 bpm in Group T. The mean arterial pressure was 85.04 ± 7.49 mmHg and 85.58 ± 6.13 mmHg, mean SpO₂ was $96.16 \pm 1.77\%$ and $96.53 \pm 1.93\%$, and mean respiratory rate was 16.27 ± 2.70 and 16.18 ± 2.92 breaths/min in Group F and Group T, respectively. At 10 minutes, the mean heart rate was 91.96 ± 11.27 bpm in Group F and 92.44 ± 11.98 bpm in Group T. Mean arterial pressure was 88.47 ± 6.32 mmHg and 87.60 ± 7.45 mmHg, SpO₂ was $96.76 \pm 1.84\%$ and $96.16 \pm 1.76\%$, and respiratory rate was 17.11 ± 2.94 and 15.91 ± 2.94 breaths/min, respectively.

At 15 minutes, the mean heart rate was 88.56 ± 11.18 bpm in Group F and 88.00 ± 9.49 bpm in Group T, while mean arterial pressure was 85.73 ± 7.46 mmHg and 86.93 ± 6.08 mmHg, respectively. The mean SpO₂ was $96.58 \pm 1.55\%$ in Group F and $96.67 \pm 1.77\%$ in Group T, and the mean respiratory rate was 16.36 ± 2.85 and 16.42 ± 3.06 breaths/min, respectively. At 20 minutes, the mean heart rate was 85.98 ± 10.94 bpm in Group F and 88.62 ± 10.93 bpm in Group T. The mean arterial pressure was 86.73 ± 6.98 mmHg and 88.51 ± 7.59 mmHg, mean SpO₂

was $96.38 \pm 1.79\%$ and $96.87 \pm 1.65\%$, and mean respiratory rate was 16.09 ± 2.56 and 16.04 ± 2.92 breaths/min in the two groups, respectively.

Table 5. Total Number of Analgesic Doses Required

Table 5 shows the distribution of the total number of analgesic doses required in the two groups. In Group F, 9 (20.0%) participants required one dose compared with 8 (17.8%) participants in Group T. Two doses were required by 12 (26.7%) participants in Group F and 10 (22.2%) participants in Group T. Three doses were required by 15 (33.3%) participants in Group F compared with 9 (20.0%) participants in Group T. Four doses were required by 9 (20.0%) participants in Group F and 18 (40.0%) participants in Group T. The overall distribution of the number of analgesic doses required differed significantly between the two groups, with a p value of 0.028.

Table 6. Incidence of Maternal Adverse Effects

Table 6 presents the incidence of maternal adverse effects among participants in the two groups. Pruritus was observed in 11 (24.4%) participants in Group F compared with 1 (2.2%) participant in Group T, and the difference was statistically significant ($p = 0.007$). Nausea and/or vomiting occurred in 5 (11.1%) participants in Group F and 1 (2.2%) participant in Group T, with a statistically significant difference ($p = 0.013$). Respiratory depression was reported in 2 (4.4%) participants in Group F, whereas no participant in Group T experienced respiratory depression, with a p value of 0.033. Hypotension occurred in 6 (13.3%) participants in Group F compared with 1 (2.2%) participant in Group T, and the difference was statistically significant ($p = 0.025$). Shivering was observed in 4 (8.9%) participants in Group F and 1 (2.2%) participant in Group T, with a p value of 0.027. Urinary retention occurred in 3 (6.7%) participants in Group F, while no case was reported in Group T, and the difference was statistically significant ($p = 0.038$).

Table 1: Baseline Demographic and Maternal Physiological Characteristics of Study Participants

Variable	Group F Fentanyl (n = 45) Mean $\pm$ SD	Group T Tramadol (n = 45) Mean $\pm$ SD	p value
Age (years)	28.96 $\pm$ 5.87	28.64 $\pm$ 5.35	0.793
BMI (kg/m ²)	25.41 $\pm$ 3.12	24.61 $\pm$ 2.98	0.204
ASA physical status	ASA II – 100%	ASA II – 100%	Not Applicable
Gestational age (weeks)	38.60 $\pm$ 1.30	39.13 $\pm$ 1.49	0.074
Cervical dilatation at insertion (cm)	3.44 $\pm$ 0.86	3.57 $\pm$ 0.98	0.510
Heart rate (bpm)	85.53 $\pm$ 9.55	87.36 $\pm$ 9.68	0.371
Mean arterial pressure (mmHg)	87.31 $\pm$ 7.86	86.47 $\pm$ 7.35	0.600
SpO ₂ (%)	96.89 $\pm$ 1.27	96.89 $\pm$ 1.45	1.000
Respiratory rate (breaths/min)	16.87 $\pm$ 2.99	16.29 $\pm$ 2.52	0.324

Table 2: Analgesia Characteristics and Visual Analogue Scale Scores at Various Stages of Labour

Variable/Stage of labour	Group F Fentanyl Mean $\pm$ SD	Group T Tramadol Mean $\pm$ SD	p value
Onset of analgesia (min)	5.76 $\pm$ 2.57	8.00 $\pm$ 3.04	<0.001*
Duration of analgesia (min)	183.67 $\pm$ 43.34	145.98 $\pm$ 52.15	<0.001*
Latent phase VAS	1.44 $\pm$ 1.37	1.56 $\pm$ 1.91	0.652
Active phase VAS	2.51 $\pm$ 1.60	2.64 $\pm$ 2.43	0.748
Full dilatation VAS	1.76 $\pm$ 1.03	1.87 $\pm$ 1.77	0.688
Crowning VAS	0.60 $\pm$ 0.78	0.72 $\pm$ 1.23	0.562

Third stage VAS	0.64 ± 0.65	0.84 ± 0.80	0.194
Fourth stage VAS	0.31 ± 0.47	0.27 ± 0.50	0.663

Table 3: Labour Outcomes, Neonatal Parameters and Mode of Delivery

Variable	Group F Fentanyl	Group T Tramadol	p value
Duration of 1st stage (min), Mean ± SD	299.40 ± 106.22	324.20 ± 98.86	0.255
Duration of 2nd stage (min), Mean ± SD	60.16 ± 28.79	62.31 ± 32.01	0.738
APGAR score at 1 min, Mean ± SD	8.13 ± 0.82	7.98 ± 0.87	0.382
APGAR score at 5 min, Mean ± SD	8.87 ± 0.82	9.02 ± 0.75	0.350
Normal vaginal delivery, n (%)	35 (77.8%)	35 (77.8%)	0.659
Instrumental delivery, n (%)	5 (11.1%)	3 (6.7%)	
LSCS, n (%)	5 (11.1%)	7 (15.6%)	

Table 4: Intrapartum Maternal Monitoring Parameters

Variable	Group F Fentanyl Mean ± SD	Group T Tramadol Mean ± SD
HR 5 min	86.89 ± 12.10	91.71 ± 12.25
BP (MAP) 5 min	85.04 ± 7.49	85.58 ± 6.13
SpO ₂ 5 min	96.16 ± 1.77	96.53 ± 1.93
RR 5 min	16.27 ± 2.70	16.18 ± 2.92
HR 10 min	91.96 ± 11.27	92.44 ± 11.98
BP (MAP) 10 min	88.47 ± 6.32	87.60 ± 7.45
SpO ₂ 10 min	96.76 ± 1.84	96.16 ± 1.76
RR 10 min	17.11 ± 2.94	15.91 ± 2.94
HR 15 min	88.56 ± 11.18	88.00 ± 9.49
BP (MAP) 15 min	85.73 ± 7.46	86.93 ± 6.08
SpO ₂ 15 min	96.58 ± 1.55	96.67 ± 1.77
RR 15 min	16.36 ± 2.85	16.42 ± 3.06
HR 20 min	85.98 ± 10.94	88.62 ± 10.93
BP (MAP) 20 min	86.73 ± 6.98	88.51 ± 7.59
SpO ₂ 20 min	96.38 ± 1.79	96.87 ± 1.65
RR 20 min	16.09 ± 2.56	16.04 ± 2.92
HR 25 min	89.62 ± 11.31	92.53 ± 11.73
BP (MAP) 25 min	86.87 ± 7.36	87.11 ± 6.94
SpO ₂ 25 min	96.49 ± 1.75	96.91 ± 1.65
RR 25 min	17.27 ± 2.73	15.89 ± 2.76
HR 30 min	88.71 ± 11.93	88.76 ± 9.77
BP (MAP) 30 min	87.13 ± 8.35	87.84 ± 7.24
SpO ₂ 30 min	96.60 ± 1.56	96.60 ± 1.67
RR 30 min	16.44 ± 2.91	16.51 ± 2.69
HR 60 min	89.04 ± 11.78	89.02 ± 11.55
BP (MAP) 60 min	88.02 ± 5.93	86.07 ± 6.80
SpO ₂ 60 min	96.49 ± 1.84	96.33 ± 1.46
RR 60 min	16.11 ± 2.83	15.67 ± 2.62

Table 5: Total Number of Analgesic Doses Required

Total doses required	Group F Fentanyl n (%)	Group T Tramadol n (%)	p value
1	9 (20.0%)	8 (17.8%)	0.028*
2	12 (26.7%)	10 (22.2%)	
3	15 (33.3%)	9 (20.0%)	
4	9 (20.0%)	18 (40.0%)	

Table 6: Incidence of Maternal Adverse Effects

Adverse effect	Group F Fentanyl n (%)	Group T Tramadol n (%)	p value
Pruritus	11 (24.4%)	1 (2.2%)	0.007*
Nausea / vomiting	5 (11.1%)	1 (2.2%)	0.013*
Respiratory depression	2 (4.4%)	0 (0%)	0.033*
Hypotension	6 (13.3%)	1 (2.2%)	0.025*
Shivering	4 (8.9%)	1 (2.2%)	0.027*
Urinary retention	3 (6.7%)	0 (0%)	0.038*

DISCUSSION

The present study showed that the baseline demographic and physiological characteristics were comparable between Group F and Group T. The mean age was 28.96 ± 5.87 years in Group F and 28.64 ± 5.35 years in Group T (p = 0.793), while the mean BMI was 25.41 ± 3.12 kg/m² and 24.61 ± 2.98 kg/m², respectively (p = 0.204). Gestational age was

38.60 ± 1.30 weeks versus 39.13 ± 1.49 weeks (p = 0.074), and cervical dilatation at insertion was 3.44 ± 0.86 cm versus 3.57 ± 0.98 cm (p = 0.510). Baseline heart rate, mean arterial pressure, SpO₂ and respiratory rate also showed no statistically significant differences. Similar baseline comparability was reported by Choudhary et al. (2020),^[7] who compared fentanyl and tramadol with low-dose ropivacaine. Their mean age was 22.54 ±

2.50 years in the fentanyl group and 22.86 ± 2.17 years in the tramadol group. They also reported no statistically significant differences in mean heart rate or arterial blood pressure between the groups ($p > 0.05$), showing a comparable baseline physiological profile between treatment groups. The principal difference observed in analgesic characteristics in the present study was a significantly faster onset and longer duration of analgesia with fentanyl.^[1] The mean onset of analgesia was 5.76 ± 2.57 minutes in Group F compared with 8.00 ± 3.04 minutes in Group T ($p < 0.001$), while the mean duration was 183.67 ± 43.34 minutes and 145.98 ± 52.15 minutes, respectively ($p < 0.001$). Tomar et al. (2011),^[8] also demonstrated the effect of adding fentanyl to 0.125% bupivacaine during epidural labour analgesia. With 20 µg fentanyl, 20 parturients achieved profound analgesia within 10 minutes, whereas maximum analgesia required approximately 15–20 minutes with the lower fentanyl dose. The duration of the first bolus analgesia was 120 ± 20.26 minutes with 20 µg fentanyl compared with 100 ± 10.04 minutes with 10 µg fentanyl and 75 ± 12.24 minutes with bupivacaine alone. Despite the difference in onset and duration of analgesia, pain scores during the different stages of labour remained comparable between the groups in the present study. The mean VAS scores in Group F and Group T were 1.44 ± 1.37 versus 1.56 ± 1.91 during the latent phase ($p = 0.652$), 2.51 ± 1.60 versus 2.64 ± 2.43 during the active phase ($p = 0.748$), 1.76 ± 1.03 versus 1.87 ± 1.77 at full dilatation ($p = 0.688$), and 0.60 ± 0.78 versus 0.72 ± 1.23 at crowning ($p = 0.562$). VAS scores during the third and fourth stages were also statistically comparable. Fan et al. (2011),^[9] similarly compared epidural 0.125% ropivacaine plus tramadol with 0.125% ropivacaine plus fentanyl and found no significant difference in VAS scores between the groups at the assessed time points ($p > 0.05$). However, unlike the present study, their onset of sensory block was 4.4 ± 0.6 minutes with tramadol and 4.6 ± 0.6 minutes with fentanyl and did not differ significantly ($p = 0.181$). Thus, their pain-score findings were similar to the present study, although the difference in onset of analgesia was not reproduced.

The duration of labour was also comparable between the two groups in the present study. The mean duration of the first stage was 299.40 ± 106.22 minutes in Group F and 324.20 ± 98.86 minutes in Group T ($p = 0.255$), while the second stage lasted 60.16 ± 28.79 minutes and 62.31 ± 32.01 minutes, respectively ($p = 0.738$). Rao et al. (2010),^[10] evaluated walking epidural analgesia using 0.1% bupivacaine with tramadol and reported a first-stage duration of 4.03 ± 1.00 hours in the epidural group compared with 6.72 ± 1.16 hours in the routine-labour group ($p < 0.001$). The second stage was 0.67 ± 0.33 hours in the epidural group and 0.55 ± 0.35 hours in the comparison group ($p = 0.072$). In their epidural tramadol group, 36/50 (72%) women delivered spontaneously, 13/50 (26%) had instrumental deliveries, and one patient underwent

caesarean section. The present study similarly did not demonstrate a significant difference between fentanyl and tramadol groups in the durations of the first or second stages of labour. Neonatal outcome and mode of delivery were comparable in the present study. The mean APGAR score at 1 minute was 8.13 ± 0.82 in Group F and 7.98 ± 0.87 in Group T ($p = 0.382$), while at 5 minutes it was 8.87 ± 0.82 and 9.02 ± 0.75 , respectively ($p = 0.350$). Normal vaginal delivery occurred in 35 (77.8%) women in each group. Instrumental delivery occurred in 5 (11.1%) women in Group F and 3 (6.7%) in Group T, while LSCS occurred in 5 (11.1%) and 7 (15.6%), respectively; the overall difference in mode of delivery was not statistically significant ($p = 0.659$). Kalra et al. (2010),^[11] studied bupivacaine-fentanyl versus bupivacaine-sufentanil for epidural labour analgesia and similarly found no significant difference in delivery or neonatal outcomes. Vaginal/forceps/caesarean deliveries were 22/2/1 in the fentanyl group and 21/3/1 in the sufentanil group, while neonatal APGAR scores were 8.41 and 8.48, respectively. Their findings also showed that a fentanyl-containing epidural regimen was not associated with a significant alteration in mode of delivery or neonatal APGAR outcome. Maternal physiological parameters remained numerically close between the two groups during intrapartum monitoring in the present study. At 5 minutes, the mean heart rate was 86.89 ± 12.10 bpm in Group F and 91.71 ± 12.25 bpm in Group T, while mean arterial pressure was 85.04 ± 7.49 and 85.58 ± 6.13 mmHg, respectively. At 30 minutes, heart rate was 88.71 ± 11.93 versus 88.76 ± 9.77 bpm and MAP was 87.13 ± 8.35 versus 87.84 ± 7.24 mmHg. At 60 minutes, heart rate was 89.04 ± 11.78 versus 89.02 ± 11.55 bpm and MAP was 88.02 ± 5.93 versus 86.07 ± 6.80 mmHg. SpO₂ remained around 96% and respiratory rates were similar throughout the reported intervals; however, no p values were provided for these intrapartum comparisons. Priyadarshini et al. (2022),^[12] likewise reported similar haemodynamic trends in two epidural ropivacaine-fentanyl regimens. Heart rate gradually decreased from baseline and subsequently stabilized, with no significant intergroup difference, while SBP, DBP and MAP also stabilized after approximately 30 minutes and showed no significant difference between groups ($p > 0.05$). Their findings were consistent with the relatively close intrapartum physiological measurements observed between the two groups in the present study. The requirement for repeated analgesic doses differed significantly between the groups in the present study. One dose was required by 9 (20.0%) women in Group F and 8 (17.8%) women in Group T, two doses by 12 (26.7%) and 10 (22.2%), and three doses by 15 (33.3%) and 9 (20.0%), respectively. Four doses were required by only 9 (20.0%) patients receiving fentanyl compared with 18 (40.0%) receiving tramadol, and the overall distribution was significantly different ($p = 0.028$). Wong et al. (2006),^[13] also demonstrated variation in

supplemental analgesic requirement according to the epidural regimen. Using bupivacaine with fentanyl 2 µg/mL, median bupivacaine consumption was 10.5 mg/hour with programmed intermittent epidural bolus compared with 12.3 mg/hour with continuous epidural infusion ($p < 0.01$). The programmed bolus group also required fewer manual rescue boluses, with a 22% difference in rescue-bolus rate. Although the maintenance techniques differed from the present study, these findings similarly demonstrated measurable differences in additional analgesic requirements between epidural regimens. Maternal adverse effects showed significant differences between the two groups in the present study. Pruritus occurred in 11 (24.4%) women receiving fentanyl compared with 1 (2.2%) receiving tramadol ($p = 0.007$). Nausea/vomiting occurred in 5 (11.1%) versus 1 (2.2%) ($p = 0.013$), respiratory depression in 2 (4.4%) versus 0 (0%) ($p = 0.033$), hypotension in 6 (13.3%) versus 1 (2.2%) ($p = 0.025$), shivering in 4 (8.9%) versus 1 (2.2%) ($p = 0.027$), and urinary retention in 3 (6.7%) versus 0 (0%) ($p = 0.038$). Chatrath et al. (2015),^[14] also observed a greater range of adverse effects in their fentanyl group. Among 30 fentanyl recipients, pruritus occurred in 7 patients, shivering in 7, nausea/vomiting in 5, transient fetal bradycardia in 5, and hypotension in 1. In their tramadol group, the only reported type of adverse effect was nausea/vomiting, occurring in 11 patients. Thus, the higher occurrence of pruritus, shivering and hypotension with fentanyl was in agreement with the pattern observed in the present study, although the distribution of nausea/vomiting differed between the two studies.

CONCLUSION

Epidural 0.1% bupivacaine with fentanyl provided a significantly faster onset and longer duration of labour analgesia compared with bupivacaine with tramadol. The fentanyl group also required fewer higher-number supplemental analgesic doses, while pain scores during different stages of labour were comparable between the groups. Maternal haemodynamic parameters, duration of labour, mode of delivery, and neonatal APGAR scores were comparable. However, maternal adverse effects were significantly more frequent with fentanyl, whereas tramadol showed a more favourable tolerability profile. Thus, both regimens were effective, with fentanyl providing more prolonged analgesia and tramadol offering fewer maternal adverse effects.

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